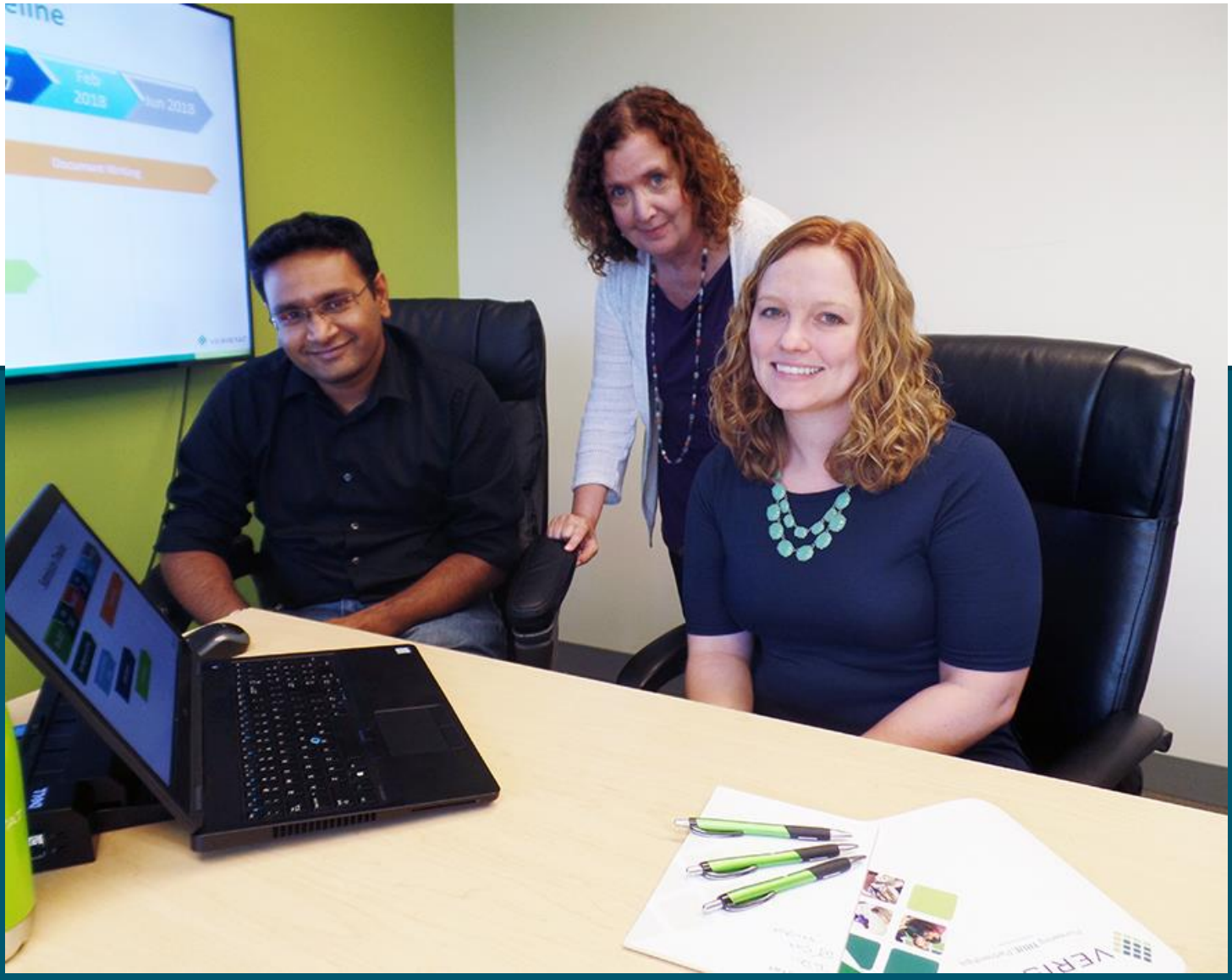
VERISTAT

# ACHIEVING AN AGGRESSIVE NDA TIMELINE

## *A Creative Approach Leads To A Regulatory Submission Success*



VERISTAT

## A Veristat Regulatory Submission Project Case Study

# ACHIEVING AN AGGRESSIVE NDA TIMELINE

### *A Creative Approach Leads To A Regulatory Submission Success*

## Background

A mid-sized biopharmaceutical firm hired Veristat to prepare and manage their New Drug Application (NDA) for the treatment of a CNS disorder that had no FDA approved therapies. The client had a 9 month timeline for Veristat to complete the submission. At the time of engagement, 2 pivotal studies were ongoing; these studies, including monitoring and data management, were being overseen by another vendor.

Veristat was contracted to provide project management, adverse event and concomitant medication up-coding, SDTM migration, biostatistics & programming, and medical writing for the NDA submission.

Database lock for both pivotal studies was delayed by 2 months without change in the submission timeline.

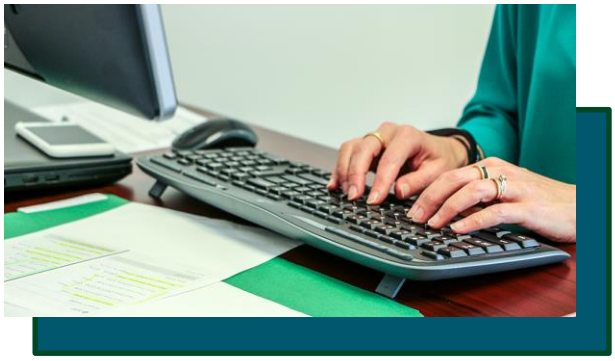
## Study Demographics

### INDICATION:

Rare Central Nervous System Disorder

### PRIMARY SERVICES PROVIDED:

Data Management (Coding), Biostatistics & Programming, CDISC Data Conversion, Medical Writing and Project Management for NDA Submission



**9 Month Timeline**

**Data Migration for**
**2 Ongoing Pivotal Studies**
**18 Legacy Studies**

**2 Month Delay**
**Receiving Final Pivotal Study Data**

## GOAL

Veristat was required to migrate legacy data into SDTM format for 18 studies, as well as convert the data for the 2 ongoing pivotal studies. The biostatistics and programming group was responsible for production of the statistical analysis plans for ISS and ISE, as well as integrated ADaM programming and production of all tables, listings and figures for the ISS and ISE. The medical writing team at Veristat produced the ISS, ISE, Module 2 clinical summaries, including M2.7.3 and M2.7.4, as well as the clinical overview M2.5.

## CHALLENGES

In order to start the analysis programming for the integrated summaries, data from each of the studies was required. Veristat received the final pivotal study data in May 2016, 2 months delayed from the original timeline.

Given the number of studies that required legacy migration to SDTM format, the 9-month timeline was aggressive making the 2-month final data delay a challenge for all Veristat teams as final statistical output for the integrated summaries, and therefore all medical writing, could not begin until receipt of final data.

## SOLUTION

Standard practice would be to migrate data on study-by-study basis. However, due to original 9-month timelines (which was only exacerbated by the 2-month delay), Veristat collaborated internally to find a solution that would allow all functional areas to work simultaneously. Based on the short timelines, the decision was made to migrate data by domain (or data type, e.g., demographics migrated for each study, adverse events migrated for each study, etc). This allowed assembly-line type production in batches – SDTM migrated the data for each domain, biostatistics and programming produced the corresponding analyses and statistical outputs for that domain, thus allowing the medical writing team to start work on the integrated summaries based on the available outputs.

Had the conventional by-study approach been used, the biostatistics and programming team would not have been able to provide final statistical outputs to medical writing until all SDTM migration was complete for all studies – thus, delaying the production of the ISS and ISE – cascading to a delay in Module 2 documents.

This non-standard approach required close collaboration across Veristat team members, with the data management vendor on the pivotal studies, and with the sponsor, all of which were critical to the success of this submission.

## THE RESULT

The NDA for this compound, which was critical to the pharmaceutical company's goals and the patients with this CNS condition, was submitted on time to the FDA, just 3 months after receipt of the final study data.

**NDA Received Priority Review Status**

**PRODUCT WAS APPROVED IN APRIL 2017**


## Contact Veristat Today

To learn more about Veristat and how we can help you achieve success with your trial or development program and regulatory submission, reach out to us today.

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